WHI Observational Study Overview

Overview
The Observational Study (OS) component of the WHI complemented the Clinical Trial (CT) by assessing new risk indicators and biomarkers for disease in a large prospective cohort of 93,676 postmenopausal women between the ages of 50 to 79. The WHI observational study (OS) had several goals. These goals included:

- To give reliable estimates of the extent to which known risk factors predict heart disease, cancers and fractures;
- To identify "new" risk factors for these and other diseases in women;
- To compare risk factors, presence of disease at the start of the study, and new occurrences of disease during the WHI across all study components; and
- To create a future resource to identify biological indicators of disease, especially substances and factors found in blood.

The OS cohort was comprised of women who were either ineligible or unwilling to participate in the CT. Over 16% of OS participants at enrollment were members of a racial / ethnic minority group. Enrollment for the OS began in 1994 and ended in 1998. OS women were followed for between 6 and 10 years, depending on when they enrolled in the study.

The major clinical outcomes of interest in the OS were coronary heart disease, stroke, breast cancer, colorectal cancer, endometrial cancer, ovarian cancer, osteoporotic fractures, diabetes, and total mortality. Most outcomes were initially ascertained by self-report on an annual questionnaire and documented by hospital and related records. Charts with potential cardiovascular, cancer, and fracture outcomes were sent to the local physician adjudicator for evaluation and classification. Staff at the Clinical Coordinating Center coded and adjudicated all cancers of major interest in the study using standardized SEER guidelines.

Follow-up
Routine follow-up activities consisted of mailings sent annually from the CCC, and a Clinical Center visit at 3 years after enrollment to update selected baseline data, obtain additional risk factor data, and collect a blood specimen. Annual mailings consisted of a cover letter, a self-administered Medical History Update to assess health outcomes, and a self-administered exposure questionnaire. Exposures collected annually varied from year to year. Up to two additional mailings and telephone contacts by Clinical Center staff were conducted for non-responders. When these efforts were not successful, clinical center staff contacted proxies to determine the location and status of the participant and to collect information on health events. Final data were collected by mail during the OS close-out period, April 2004 to March 2005.

The annual follow-up response rate was over 94% each year for those who were due for a follow-up contact. At the year 3 clinic visit, 96% completed medical history updates and 83% provided blood samples. A participant was considered lost-to-follow-up if there was no outcomes information from the participant for 24 months. At the end of the close-out period, 4.1% were either lost-to-follow-up or had stopped follow-up, and 6.1% were deceased.